

Provider Education

Medicare Part B



Investigational Device Exemption

Medicare covers certain medical devices (and services related to those devices) that are being studied as part of a Food and Drug Administration (FDA) approved clinical trial, but have not been approved for marketing. The requirements of coverage for the Investigational Device Exemption (IDE) and the CMS regulatory requirements are available in Title 42 Code of Federal Regulations.

Background

The Social Security Act (the Act) provides Medicare coverage for broad categories of benefits through both Part A and Part B of Medicare. The Act does not, however, provide an all-inclusive list of covered items, services, treatments, procedures or technologies.

Congress vested the Secretary with the responsibility to make coverage determinations when the Act is silent. These determinations are to be made using Section 1862(a)(1)(A) of the Act, which requires:

- a) the service to be reasonable and necessary for the diagnosis and treatment of illness and
- b) that the service must not be excluded elsewhere in the Act.

Historically, CMS has interpreted the statutory terms “reasonable” and “necessary” to mean that a device must be safe and effective, medically necessary, and not experimental. For most Medicare coverage purposes, the term experimental has been used synonymously with the term investigational.

Therefore, a device categorized by the Food, Drug and Cosmetic Act (21 U.S.C.360c) as being investigational served as indication that it was not “reasonable” and “necessary” within the meaning of the Medicare Program. There is increasing recognition, however, that there are devices that are refinements of existing technologies or replications of existing technologies by other manufacturers.

The Food, Drug and Cosmetic Act (FDA) places many of these devices within the investigational device exemption (IDE) category as a means of gathering the scientific information necessary to establish the safety and effectiveness of the particular device, even though there is scientific evidence that similar devices can be safe and effective.

Expansion of Policy

Under the Food, Drug and Cosmetic Act devices fall into one of three classes:

Class I

These are devices that the FDA has determined need to be subject only to general controls, such as good manufacturing practice regulations.

Class II

Devices that, in addition to general controls, require special controls, such as performance standards or post-market surveillance, to provide a reasonable assurance of safety and effectiveness.

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Class III

Devices that cannot be classified into Class I or Class II because insufficient information exists to determine that either special or general controls would provide reasonable assurance of safety and effectiveness. Class III devices require pre-market approval (PMA).

Two categories have been developed to help the FDA classify IDE's as they are being studied in clinical trials. They are as follows:

Category A

Experimental

These are innovative devices believed to be in Class III for which the absolute risk of the device type has not been established and initial questions of safety and effectiveness have not been resolved. The FDA is unsure whether these device types can be safe and effective. The CMS does not cover Category A devices under Medicare because they do not satisfy the statutory requirement that Medicare pay for devices determined to be reasonable and necessary.

Category B

Non-Experimental/Investigational

These consist of those types of devices that are newer generations of proven technologies. Initial questions of safety and effectiveness of these devices have been resolved. These devices are believed to be in classes I or II or devices believed to be in Class III where the incremental risk is the primary risk in question (i.e., underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type. The CMS may cover Category B devices if they are considered reasonable and necessary and if all other applicable Medicare coverage requirements are met.

Coverage Requirements

Medicare may cover certain FDA-approved and Institutional Review Board (IRB) approved investigational devices and services incident to, provided the investigational device meets the following conditions:

- Appears on the listing of devices eligible for coverage/payment on CMS' master file of IDE devices;
- Is reasonable and necessary for the individual patient;
- The device or services associated with the use of a device were provided to the beneficiary within the start and end dates contained in the master file; and,
- There is no national coverage policy that would otherwise prohibit Medicare coverage.

Devices that may be covered under Medicare include the following categories:

- Devices approved by the FDA through the Pre-Market Approval (PMA) process;
- Devices cleared by the FDA through the 510(k) process;
- FDA-approved IDE Category B devices; and
- Hospital Institutional Review Board (IRB) approved IDE devices

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It is the responsibility of the provider participating in the clinical trial to furnish all necessary information concerning the device, the clinical trial, the participating Medicare beneficiaries that will be participating in the clinical trial, and the site where the trial(s) will be conducted.

The following criteria will be applied when making coverage determinations on FDA-approved IDE Category B devices:

- The device must be used within the context of the FDA-approved clinical trial;
- The device must be used according to the clinical trial's approved patient protocols;
- There may be an established national policy as contained in existing manual instructions, e.g., National Coverage Determinations Manual instructions, etc.;
- In the absence of national policy, there may be a local policy for similar FDA-approved devices;
- There may be Policy/Position papers or recommendations made by pertinent national and/or local specialty societies.

Contractors will also consider, among other factors, whether the device is:

- Medically necessary for the particular patient and whether the amount, duration, and frequency of use or application of the service are medically appropriate; and
- Furnished in a setting appropriate to the patient's medical needs and condition.

This policy does not provide coverage for any devices that would otherwise not be covered by Medicare; e.g., statutorily excluded devices or items and services excluded from coverage through regulation or current manual instructions.

FDA Approval of IDEs

The FDA will issue a special identifier number (IDE number) that corresponds to each device granted an IDE. The number will enable Medicare contractors to establish special processing procedures associated with each study. The IDE number is alphanumeric (one alpha and six numeric) and must be obtained from the manufacturer supplying the device in the clinical trial.

Billing Requirements

When billing for IDE services, you must use the appropriate HCPCS code.

Enter the IDE number assigned to the device in Item 23 of the CMS-1500 claim form (or in the appropriate field for electronic claims). Providers may also provide a copy of their approval letter to substantiate their claim for payment, though this is not mandatory.

Modifier "Q0" must be used to identify claims for investigational clinical service provided in a clinical research study that is in an approved clinical research study. The Q0 modifier replaces the QA and QR modifier effective January 1, 2008. Enter the modifier Q0 in Item 24D of the CMS-1500 claim form or the electronic equivalent.

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Modifier “Q1” must be used to identify claims for routine clinical service provided in a clinical research study that is in an approved clinical research study. The Q1 modifier replaces the QV modifier effective January 1, 2008. Enter the modifier Q1 in Item 24D of the CMS-1500 claim form or the electronic equivalent.

Providers should use these two new modifiers as follows:

- Investigational clinical services are defined as those items and services that are being investigated as an objective within the study. Investigational clinical services may include items or services that are approved, unapproved, or otherwise covered (or not covered) under Medicare.
- Routine clinical services are defined as those items and services that are covered for Medicare beneficiaries outside of the clinical research study.
- Routine clinical services are used for the direct patient management within the study and do not meet the definition of investigational clinical services.
- Routine clinical services may include items or services required solely for the provision of the investigational clinical services (e.g., administration of a chemotherapeutic agent), clinically appropriate monitoring, whether or not required by the investigational clinical service (e.g., blood tests to measure tumor markers), and items or services required for the prevention, diagnosis, or treatment of research related adverse events (e.g., blood levels of various parameters to measure kidney function).
- Medicare contractors will not search their files to adjust affected claims processed prior to implementation of this change, but they will adjust such claims that providers bring to their attention.

Appeals Under Medicare Part B

Any manufacturer that does not agree with the FDA decision that categorizes its device as Category A (experimental) may submit a written request asking the FDA to re-evaluate its categorization decision. The sponsor (manufacturer) may send a written request to FDA at any time asking for a re-evaluation of its original categorization decision, submitting any additional evidence and information which it believes supports a recategorization. The FDA will notify both CMS and the sponsor (manufacturer) of its reevaluation decision.

If the FDA reconfirms its original decision on the categorization of the device, the sponsor (manufacturer) may seek a review by CMS Central Office. The device sponsor (manufacturer) must submit its request in writing, and must include all materials submitted with its re-evaluation request to FDA. Review requests must be addressed to:

Centers for Medicare & Medicaid Services
IDE Categorization Review, Office of Clinical Standards and Quality Coverage and
Analysis Group
7500 Security Blvd.

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CMS staff will then review this information to determine whether to change the categorization of the device. CMS will then issue a written decision notifying both the device sponsor (manufacturer) and the FDA of its decision. In evaluating a manufacturer's request for recategorization CMS will only review the information submitted to the FDA. Information not submitted to FDA for its consideration will not be reviewed by CMS.

To the extent that CMS relies on confidential commercial or trade secret information in its review, the Agency will maintain confidentiality of the information in accordance with Federal law. No reviews of a categorization decision other than those described above are available to a sponsor (e.g., a manufacturer). Neither the FDA original categorization decision or reevaluation nor CMS' review constitutes an initial determination for purposes of the Medicare appeals processes under part 405, subpart G or subpart H or parts 417, 473, or 498 of title 42 of the Code of Federal Regulations.

Limitation on Liability

The basis for coverage and non-coverage of certain investigational devices and services related to those devices is 1862(a)(1)(A) of Title XVIII of the Social Security Act and the corresponding regulations found in 411.15(K) 42 CFR. Medicare payment may be made for assigned claims for a service related to a noncovered device under certain conditions.

Specifically, a beneficiary who did not know and could not reasonably have been expected to know that payment would be denied under section 1862(a)(1)(A) of the Act receives protection from financial liability. If payment is denied for this reason, the Medicare beneficiary has limited liability to pay for the service, because he could not have been expected to know at the time that Medicare would not pay.

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Any physician who provides services that he knows, or could reasonably be expected to know is not medically necessary and reasonable, is required to notify the patient in writing before performing the service. This notice is called an "Advance Beneficiary Notice" (ABN). Without a properly signed ABN, a service denied as not medically necessary and reasonable **can not** be billed to the patient.

For unassigned claims for related physician services excluded from coverage as not medically necessary under section 1862(a)(1)(A) of the Act, a beneficiary who did not know and could not reasonably have been expected to know that payment would be denied as not medically necessary may receive protection from financial liability. If the beneficiary is found not to have known, and the provider or supplier also did not know and could not reasonably have been expected to know that payment would be denied, the provider or supplier will receive protection from financial liability under the refund requirement provision.

Reference: CMS Manual 100-2; Ch.14; 42CFR

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Revision History

Version	Date	Reviewed By	Approved By	Summary of Changes
1	9/29/2004	Amy Randall	Brenda Bedard	Original Guide
2	4/19/2007	B. Bedard / R Reed-Knighton	B. Bedard / R Reed-Knighton	ANNUAL REVIEW – Added information on where to place QA modifier on claim.
3.0	5/29/2008	B. Bedard/ A. Randall	M. Kelly/K. Leary	ANNUAL REVIEW – reformatted on article template. No content changes needed.
4.0	6/11/2009	B. Bedard	M. Clark	ANNUAL REVIEW – Updated the article to include new modifiers and instructions.

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